K063344

This summary statement complies with 21CFR, section 807.92(c).
Date summary prepared: 20 September 2006

NOV 28 2006

This premarket notification has been submitted by Pie Medical Imaging BV and covers the CAAS QCA 3D software package. Pie Medical Imaging is located at:

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The contact person is: Ms. Carla de Vries, Quality Assurance Officer

The trade name is:
CAAS QCA 3D
The common name for this type of device is:
Cardiovascular Angiography Analysis System Quantitative Coronary Analysis 3D
and the classification name is:
Image Processing System (LLZ).

The above as stated in 21 CFR, part 892.1570, has been classified as regulatory Class II.

The CAAS QCA 3D software package is substantially equivalent to the CAAS system known under FDA number K052988.

The CAAS QCA 3D is one of the software modules intended to run on the Cardiovascular Angiography Analysis System mark, CAAS. It functions in the same manner as other vascular analysis software packages.
The QCA-3D module allows accurate and reproducible quantification of the coronary arteries from a set of angiographic X-ray images. The analyst selects between 2 and 5 angiographic images obtained from different X-Ray projections. On each of the images a classic 2D arterial detection is performed, after which from all images a reconstruction of the arterial segment is obtained in 3D space. Indication of a common point in each of the images is used to obtain an exact spatial relationship between the images. After the selection of the arterial segment of interest the contour of this arterial segment is automatically detected. Based on the contour information a number of analysis results can be calculated.
Three analysis methods are available: The first method is an automatic reconstruction of the diseased arterial vessel by means of computing the reference along the arterial vessel to reconstruct the healthy arterial vessel, calculation of main result the % of stenosis. The ~~second me~~thod allows for manual definition of the reference along the arterial segment by means of selecting one or more reference positions in the arterial segment, calculation of main result the % of stenosis. The third analysis method enables the user to define one or more subsegments, within each user defined subsegment the minimum, maximum and mean area are calculated.
Besides area information also diameter results for each image used to reconstruct the vessel into 3D space are calculated over the arterial positions of interest. These diameter results will be corrected for out of plane calibration and length measurements will be corrected for foreshortening errors.
The indications for use remain the same. CAAS consists of reused algorithms with the addition of several improvements that do not influence the indications for use.

The intended use of the CAAS QCA 3D is:

1. Optimizing the quantification of artery dimensions – to be used in clinical trials and in clinical cath lab environment
2. Management of data resulting of the quantitative analysis

The CAAS QCA 3D is equivalent in technological characteristics to the predicate device mentioned in this summary:

- The automatic contour detection of the CAAS QCA 3D software is similar to the contour detection algorithms used in the predicate device.
- The CAAS QCA 3D software produces similar results as the predicate device.

CAAS QCA 3D is produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

The CAAS QCA 3D software package is substantially equivalent to:

- K052988 CAAS system

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NOV 28 2006

Ms. Carla de Vries
Submission Correspondent
Pie Medical Imaging bv
Becanusstraat 13D
6216 BX Maastricht
THE NETHERLANDS

Re: K063344
Trade/Device Name: CAAS QCA 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 26, 2006
Received: November 6, 2006

Dear Ms. de Vries:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Notification - CAAS QCA 3D

INDICATION FOR USE STATEMENT ***page 1 of 1***

510(k) number (if known): K063344

Device Name: CAAS QCA 3D

Indications For Use:

Detect the contour of the coronary vessel from a set of angiographic X-ray images – Generate absolute measurements about the dimensions of the coronary arterial segment in 3D space to improve accuracy by elimination of out-of-plane and foreshortening errors.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063344